MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Oxytocin 20 IU/mL Intravenous Injection (Solution, 100 mL)	FIN	F 006 954v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Oxytocin 80 Units/mL Stock Solution †	25.00	mL				
Sterile Sodium Chloride (0.9%) Injection, USP	70.0	mL				
Sterile Sodium Chloride (0.9%) Injection, USP	q.s. to 100.0	mL				
† **Oxytocin 80 Units/mL Stock Solution**						
Oxytocin, USP	8,000	Units				
Sterile Sodium Chloride (0.9%) Injection, USP	80.0	mL				
Sterile Sodium Chloride (0.9%) Injection, USP	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic *(protect from moisture whenever possible):* *Oxytocin*

Light Sensitive *(protect from light whenever possible):* *Oxytocin*

Suggested Preparatory Guidelines

☐ Non-Sterile Preparation ■ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error, sterility and endotoxin testing considerations during preparation, it is suggested to measure an additional **5 to 9%** of the required quantities of ingredients.

Special Instruction: This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 797*. Only trained and qualified personnel must prepare this formula.

All heat stable, reusable materials and equipment must be sterilized and depyrogenated by dry heat sterilization at 250°C for 2 hours prior to use.

Every batch of final product compounded using this procedure must be sterility and endotoxin tested before being dispensed.

Protective apparel, such as a sterile gown, sterile gloves, shoe covers, head cap, eyewear and face-masks should always be worn. In addition, proper personnel cleansing must be done before entering the buffer or clean area.

Filter integrity must be validated by performing a filter stress test. If the test demonstrates that the filter might be defective, the solution must be discarded and remade.

This procedure requires the use of very small quantities of ingredients. All calculations and preparation techniques must be verified before dispensing the final product.

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SUGGESTED PREPARATION (for 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Oxytocin 80 Units/mL Stock Solution † §	25.00	mL			
Sterile Sodium Chloride (0.9%) Injection, USP §	70.0	mL			
Sterile Sodium Chloride (0.9%) Injection, USP §	q.s. to 100.0	mL			
† **Oxytocin 80 Units/mL Stock Solution**					
Oxytocin, USP §	8,000	Units	---	---	
Sterile Sodium Chloride (0.9%) Injection, USP §	80.0	mL	---	---	
Sterile Sodium Chloride (0.9%) Injection, USP §	q.s. to 100.0	mL	---	---	

* Takes into account increased batch size conversions and density conversions, if required.
§ Weigh / measure just prior to use.

Preparatory Instruction

IMPORTANT: All preparatory procedures must be performed using proper Aseptic Technique

1. **Equipment sterilization:**

   Following the manufacturer's specifications, sterilize and depyrogenate all heat stable, reusable materials and equipment, then return to ambient temperature.

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2. **Ingredient quantification (units per weighted measure adjustment):**

A. Determine the quantity (in g) of Oxytocin required to make an Oxytocin 80 Units/mL Stock Solution, batch size (100.0 mL):

Quantity of Oxytocin (in Units) required	8,000 IU
DIVIDED BY	
Oxytocin biopotency assay result (from Certificate of Analysis)	_____ IU/mg
EQUALS	
Quantity of Oxytocin (in milligrams) required	_____ mg
MULTIPLIED BY	
Multiplication factor – milligrams to grams	0.001
EQUALS	
Quantity of Oxytocin (in grams) required for the Stock Solution	_____ **g**

3. † **Oxytocin 80 units/mL Stock Solution preparation:**

A. Incrementally add the Oxytocin (amount determined in Step 2A) to the Sterile Sodium Chloride (0.9%) Injection (80.0 mL).

Specifications: Continuously mix until all solid particles have completely dissolved.

End result: Homogeneous liquid-like solution.

B. Add additional Sterile Sodium Chloride (0.9%) Injection to the mixture (Step 3A) to fill to the required amount (100.0 mL).

End result: Homogeneous liquid-like solution.

4. **Powder-liquid preparation**:

A. Incrementally add the Oxytocin 80 units/mL Stock Solution (25.00 mL *plus* processing error adjustments) to the Sterile Sodium Chloride (0.9%) Injection (70.0 mL *plus* processing error adjustments).

Specifications: Continuously mix until homogeneous.

End result: Homogeneous liquid-like solution.

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5.	**Filling to volume:** A. Add additional Sterile Sodium Chloride (0.9%) Injection to the above mixture to fill to the required batch size (100.0 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like solution.
6.	**Filtering and transferring:** Aseptically filter the solution through a 0.22-µm sterile filter into the recommended dispensing containers (see Packaging requirements). Transfer the remainder into a separate dispensing container. This is to be used as the Test sample for sterility and endotoxin testing.
7.	**Filter integrity test:** Validate filter integrity by performing a filter stress test. If the test demonstrates that the filter might be defective, the solution must be discarded and remade.
8.	**Sterility testing:** Validate the Test sample for sterility and endotoxin, in accordance to current USP 797 regulatory guidelines.

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated, as per USP 797. BUD based on a successful sterility and endotoxin test result.	Packaging Requirements		Sterile, tightly closed, light-resistant unit-dose injection vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7		Protect from light.
	2	Keep out of reach of children.	8		Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	Cap tightly after use.	9		Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	4	Keep refrigerated. Do not freeze.	10		Discard container after use.
	5	Do not use if product changes color.	11		Discard in the presence of particulate matter.
	6	Equilibrate to room temperature before use.			
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.				
Patient Instructions	If allergic reactions occur, consult your pharmacist.				

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REFERENCES

1.	Parenteral Preparations. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition.* American Pharmaceutical Association; 2012: 313.
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